UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

BIG TIME VAPES, INC., *et al.*,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,[1]

Defendants.

Civil Case No. 1:19-cv-531-LG-JCG

DEFENDANTS' COMBINED MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

[1] Admiral Brett P. Giroir, M.D., is now the Acting Commissioner of Food and Drugs, and is therefore automatically substituted as a defendant in his official capacity for Dr. Norman E. Sharpless, M.D., pursuant to Federal Rule of Civil Procedure 25(d).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

UNITED STATES CONSTITUTION

OTHER AUTHORITIES

INTRODUCTION

The Constitution's "limits on delegation are frequently stated, but rarely invoked: the Supreme Court has not struck down a statute on nondelegation grounds since 1935." *United States v. Whaley*, 577 F.3d 254, 263 (5th Cir. 2009). Over the past 84 years, the Supreme Court "has over and over upheld even very broad delegations." *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality opinion). Undeterred by this consistent precedent, Plaintiffs argue that the Tobacco Control Act has impermissibly delegated authority to the Executive Branch to implement and enforce the statute's definition of "tobacco product"—a statutory term that is defined with specificity, but that also leaves some residual flexibility for the Food and Drug Administration to bring new "tobacco products" within the statute's coverage to execute Congress's policy goals. But settled precedent permits even broad delegations, as long as Congress provides some "intelligible principle." *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). The Tobacco Control Act readily satisfies that standard.

Plaintiffs manufacture and sell electronic cigarettes. Commonly known as "e-cigarettes" or "vaping" devices, these novel products now comprise the fastest growing segment of the tobacco market, and their use has spiked dramatically in recent years. They are now used by more than 25% of high-school students, eclipsing conventional cigarettes as the most popular tobacco product among youth. And notwithstanding many misconceptions, vaping presents significant public-health risks.

To start with what we know, e-cigarettes are designed to deliver nicotine—one of the most addictive substances known to man—and can do so at least as effectively as conventional cigarettes. Nicotine is toxic, impairs brain development in youth, causes pre-term delivery and stillbirth, and can be fatal at high doses. Some e-cigarettes also deliver other toxic and carcinogenic chemicals at levels higher than conventional cigarettes. Others have exploded in users' faces, causing burns and lost teeth. And while the physiological effects of the myriad ingredients in the thousands of e-liquids on

the market remain largely unknown, many contain diacetyl, acetyl propionyl, or various aldehydes—chemicals that are known to be toxic, and that are especially common in candy-flavored varieties that appeal directly to youth. Perhaps more troubling still is what we do *not* know about e-cigarettes, and their effects on both adult and youth users (not to mention those breathing in their aerosolized vapor, secondhand). There is necessarily limited data about the long-term effects of these varied and novel products, and with each passing day, physicians and scientists sound the alarm even more loudly about their short-term safety on the front pages of newspapers[2] and medical journals[3] across the globe.

The Tobacco Control Act applies to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," but also "to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b). Accordingly, in 2016, faced with substantial uncertainty (at best) about the safety of e-cigarettes, the Secretary (through his subordinates at the FDA) exercised this statutory authority to issue, through notice-and-comment rulemaking, a regulation now colloquially known as the "deeming rule," which subjected e-cigarettes (among other tobacco products) to the requirements of the Tobacco Control Act. That rule, in combination with the Tobacco Control Act itself, provides the regulatory foundation for FDA's oversight of the e-cigarette industry, in furtherance of Congress's desire "to ensure that the Food and Drug

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[2] *See, e.g.*, Brianna Abbott, *'The Bells Start Going Off.' How Doctors Uncovered the Vaping Crisis.*, THE WALL STREET JOURNAL (Sept. 23, 2019), *available at* https://www.wsj.com/articles/the-bells-start-going-off-how-doctors-uncovered-the-vaping-crisis-11569252950 (as of September 23, 2019 "[h]ealth authorities now count 530 confirmed and probable cases of the vaping-related illness across 38 states and one U.S. territory," and "[e]ight people have died"); *see also* Centers for Disease Control and Prevention, *Outbreak of Lung Injury Associated with E-Cigarette, or Vaping, Products* (Oct. 31, 2019) (as of October 29, 2019, 1,888 lung injury cases in 49 states, with 37 confirmed deaths in 24 states), *available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

[3] *See, e.g.*, David V. Christiani, M.D., M.P.H., *Vaping-Induced Lung Injury*, THE NEW ENGLAND JOURNAL OF MEDICINE (Sept. 6, 2019), *available at* https://www.nejm.org/doi/full/10.1056/NEJMe1912032 ("[E]fforts should be made to increase public awareness of the harmful effect of vaping, and physicians should discourage their patients from vaping.").

Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 § 3(2), 123 Stat. 1776, 1781 (2009). Plaintiffs' requested relief—vacatur of the deeming rule in its entirety—would thus result in e-cigarettes no longer being subject to federal regulatory scrutiny *at all*. Among many other things, there would no longer be any federal prohibition on the sale of vaping products to minors.

Although Plaintiffs are—perhaps tellingly—the first to bring a challenge to the deeming rule under the nondelegation doctrine, these claims are just as meritless (or more so) as the many other challenges to the rule that FDA has successfully defended since 2016 (including from those, unlike Plaintiffs here, who asserted their rights in a timely manner). And at the very least, Plaintiffs have not carried their burden to demonstrate entitlement to a preliminary injunction, "an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). This lawsuit ultimately represents only the most recent of a long history of attempts by the tobacco industry to delay regulatory scrutiny of its dangerous products for as long as possible, while yet another generation of teenagers becomes addicted to nicotine. This Court should not indulge that project further.

BACKGROUND

A. Congress studies the dangers of tobacco products.

Congress enacted the Tobacco Control Act in 2009, based on evidence compiled over decades by all three branches of government about the health risks of tobacco products and the tobacco industry's marketing practices. The evidence before Congress at that time established four key points:

First, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). "Each year, 440,000 people die of diseases caused by smoking or other forms

of tobacco use—that is about 20 percent of all deaths in our nation." 155 Cong. Rec. S6000 (2009) (statement of V. Admiral Richard H. Carmona, U.S. Surgeon General).

Second, tobacco's public-health harm is "inextricably linked" to nicotine addiction. 75 Fed. Reg. 69,524, 69,528 (Nov. 12, 2010). "The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.* The power of nicotine addiction is perhaps best illustrated by the failure rate of cessation efforts. In 2004, over 40% of adult smokers reported trying to quit; only 3-5% were successful. *Id.* at 69,529. The tobacco industry has long appreciated the importance of nicotine addiction to sales. In an internal memo, one company acknowledged that "a tobacco product is, in essence, a vehicle for the delivery of nicotine"—a "potent drug with a variety of physiologic effects"—and that the "industry is then based upon the design, manufacture, and sale of attractive forms of nicotine." 146 Cong. Rec. H1849 (2000) (statement of Rep. Ganske) (quoting a 1972 memo from R.J. Reynolds).

Third, the tobacco industry has long depended on recruiting underage users who become addicted before age 18. The "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Leg. Finding 31, Pub. L. No. 111-31, § 2, 123 Stat. 1776, 1779 (2009) (*codified at* 21 U.S.C. § 387 (notes)). Congress also found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." *Id.* at 1777 (Finding 15).

Fourth, for decades, the tobacco industry misled its customers and the general public about the health risks and addictiveness of its products. In 1964, the Surgeon General began issuing reports on the health consequences of tobacco use and nicotine addiction. In response, tobacco companies undertook a campaign to deny these health hazards and attack those studies—even though they knew

they were accurate. These efforts are "demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 855 (D.D.C. 2006), *aff'd in part*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam).

At the same time, tobacco companies sought to develop "health reassurance" products purporting to pose lower health risks, provide an alternative to quitting, or represent a step in decreasing the level of dependence. *Philip Morris*, 566 F.3d at 1107. The companies knew, however, that these supposedly less harmful products actually provided no health benefit. Indeed, tobacco companies "marketed and promoted their low tar brands to smokers—who were concerned about the health hazards of smoking or considering quitting—as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." *Id.*

B. Congress enacts the Tobacco Control Act.

Against this backdrop, in 2009, Congress amended the Federal Food, Drug, and Cosmetic Act ("FDCA") by enacting the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA" or "the Act") as a comprehensive scheme to regulate "tobacco products." Pub. L. No. 111-31, 123 Stat. 1776 (2009) (*codified at* 21 U.S.C. § 301 *et seq.*). In addition to a series of 49 congressional findings about the dangers posed by tobacco products, *see id.* § 2, the text of the Act includes ten explicit statements about Congress's purposes, one of which was "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco." *Id.* § 3(2).

Congress furthered these purposes in other statutory provisions that authorize the Secretary of Health and Human Services ("HHS") and his subordinates at the FDA to implement Congress's

goals. As particularly relevant here, Congress made the statute applicable to not just "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco,"[4] but also "to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b). In addition, "[t]he Secretary may by regulation require restrictions on the sale and distribution of tobacco products . . . if the Secretary determines that such regulation would be appropriate for the protection of the public health." *Id.* § 387f(d)(1).

In practice, the Tobacco Control Act advances several of Congress's policy goals in four main ways. First, Congress required disclosure of accurate information about "tobacco products" and their health risks. Manufacturers of tobacco products must disclose to the FDA the identity and quantity of all ingredients—including nicotine and other additives—in each product. *Id.* § 387d(a)(1)-(2). Product labels must accurately describe their contents. *Id.* § 387c. Tobacco products may be required to bear warnings about addictiveness and other risks. *Id.* § 387f(d)(1)-(2); 15 U.S.C. § 4402(a)(1). And to ensure that products marketed as having reduced health risks actually do, Congress prohibited so-called "modified risk" claims without FDA authorization. 21 U.S.C. § 387k.

Second, the Act regulates the contents of "tobacco products." Manufacturers must register with the FDA, *id.* § 387e(b), and file a list of the tobacco products that they make, *id.* § 387e(i). Given the particular appeal of flavored products to children, Congress banned the use of all characterizing flavors (except tobacco and menthol) in cigarettes. *Id.* § 387g(a)(1)(A). Congress also authorized the FDA to adopt standards regulating the level of any ingredient, including nicotine. *Id.* § 387g(a)(3).

Third, to prevent potentially harmful "tobacco products" from saturating the market and addicting new generations of youth users before regulators can catch up—that is, to prevent what

[4] Each of those four listed "tobacco products" also have their own definitions. *See* 21 U.S.C. § 387(3) (cigarette), (4) (cigarette tobacco), (15) (roll-your-own tobacco), and (18) (smokeless tobacco).

happened to generations past with conventional, combustible cigarettes—the Tobacco Control Act requires any manufacturer to obtain premarket authorization from the FDA *before* introducing any "new tobacco product" (*i.e.*, a "tobacco product" not commercially marketed in the United States as of February 15, 2007) into interstate commerce. *Id.* § 387j(a)(1)-(2). A manufacturer may seek premarket authorization through one of three pathways: by submitting (1) a "premarket tobacco application" (or "PMTA") demonstrating that the sale of the product would be "appropriate for the protection of the public health," *id.* § 387j(b)-(c); (2) a "report" establishing that the product is "substantially equivalent" to a predicate product, *id.* §§ 387j(a)(2)(A)(i), 387e(j)(1); or (3) a request for an "exemption" from the substantial equivalence requirement, *id.* §§ 387j(a)(2)(A)(ii), 387e(j)(3).[5]

Fourth, Congress reinstated a modified version of a 1996 rule restricting tobacco industry marketing practices to youth. *Id.* § 387a-1(a). For cigarettes and smokeless tobacco, the reinstated rule bans the sponsorship of concerts and athletic events in the name of a tobacco brand, and bars the distribution of merchandise bearing a tobacco brand name or logo. 21 C.F.R. § 1140.34(a), (c). And the rule generally bans the distribution of free samples of any tobacco product. Pub. L. No. 111-31, § 102(a)(2)(G); 21 C.F.R. § 1140.16(d).

Thus, although Congress delegated to the FDA authority to "deem[]" "any other tobacco products" "to be subject" to the requirements in the statute, 21 U.S.C. § 387a(b)—that is, as long as the deemed product also satisfies the definition of "tobacco product" in 21 U.S.C. § 321(rr)(1)—the core substantive obligations on manufacturers (including premarket review obligations) come from

[5] The FDA expects that e-cigarette manufacturers who wish to sell their products in a manner consistent with the TCA will generally use the "premarket tobacco application" or "PMTA" process, as it is unclear that any relevant predicate products were on the market as of February 2007 for use with the substantial equivalence pathway. *See* 81 Fed. Reg. at 28,978.

the TCA itself, with FDA authorized to implement and enforce those congressionally imposed obligations.

C. The FDA studies the risks of e-cigarettes.

After extensive study, the FDA first exercised its authority to regulate e-cigarettes in 2016. The record before the agency at that time showed that e-cigarette use had recently spiked, especially among minors, and raised significant public health concerns.

E-cigarettes first appeared in China in the early 2000s and were available in the United States by 2007. 81 Fed. Reg. 28,974, 28,978 (May 10, 2016) ("Deeming Rule"). The earliest devices were "cigalikes," so named for their resemblance to conventional cigarettes. *Id.* Later variations came to be known as "vaping" devices, or "vapes." Despite design variations, all e-cigarettes generally share three basic parts: a cartridge of liquid typically containing nicotine ("e-liquid"), an atomizer with a heating element, and a battery and other electronics. *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010). When a user sucks on the device, the atomizer vaporizes the e-liquid, which is inhaled as an aerosol. *Id.* They are often referred to as e-cigarettes or—reflecting their primary function—electronic nicotine delivery systems ("ENDS"). *See, e.g.*, Deeming Rule, 81 Fed. Reg. at 28,976.

E-cigarette use in the United States was negligible in the 2000s, but has risen dramatically since. *Id.* at 29,028-29,029. By 2014, e-cigarettes had eclipsed conventional cigarettes as the most widely used tobacco product among youth, with more than 2.4 million users in middle and high school. *Id.* at 28,984. The e-cigarette market ballooned in tandem, with domestic sales surpassing $3 billion in 2015. E-cigarettes are sold alongside conventional cigarettes in supermarkets, pharmacies, convenience stores, and "big box" retailers, as well as online and in many thousands of "vape shops"

across the country. All told, at the time of the deeming rule, some 640-800 different e-cigarette devices were being sold in the United States.[6] Many more are sold today.

In contrast to conventional cigarettes, which can only contain one of two characterizing flavors (tobacco and menthol), e-liquids were sold in the United States in 4,000-8,000 different varieties when the deeming rule issued. Deeming Rule RIA, 76-78. Many of these were fruit or candy flavored—with names like "Cherri Bombz," "Cereal Treats Loopz," or "Heavy Custard Unicorn Cake"[7]—magnifying "their appeal to youth and young adults." Deeming Rule, 81 Fed. Reg. at 29,011.

Notwithstanding pervasive misconceptions about their safety, this explosion of novel and varied tobacco products has raised significant public-health concerns. Although the FDA has long recognized that, for some adult smokers who are already addicted to conventional cigarettes, completely switching to e-cigarettes has the potential to reduce the risk of some tobacco-related diseases—cigarettes, after all, are one of the deadliest products ever brought to market—FDA found that e-cigarettes still pose significant health and safety risks of their own, 81 Fed. Reg. at 29,047:

> **1. Addictiveness of Nicotine**: Nicotine is "one of the most addictive substances used by humans," *id.* at 28,988, and "a powerful pharmacologic agent that acts in the brain and throughout the body," Surgeon General's Report (1988) at 14.[8] "[N]icotine

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[6] FDA, *Final Regulatory Impact Analysis: Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act*, FDA Docket No. 2014-N-0189 (May 2016) ("Deeming Rule RIA") at 76, *available at* https://www.fda.gov/media/97875/download.

[7] FDA, Warning Letter to DC Laboratories Inc., d/b/a Dynamic Creations (Apr. 9, 2019), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/dc-laboratories-inc-dba-dynamic-creations-565520-04092019; FDA, Warning Letter to Electric Lotus, LLC (Nov. 29, 2018), *available at* https://www.fda.gov/inspections-compliance-enforcementand-criminal-investigations/warning-letters/electric-lotus-llc-568710-11292018.

[8] Joint Appendix ("JA") 207, *Moose Jooce v. FDA*, No. 18-cv-203-CRC (D.D.C.), ECF No. 34-2. In challenges to agency action arising under the Administrative Procedure Act, judicial review is generally confined to the administrative record compiled by the agency and submitted to the court. *See, e.g.*, *Camp v. Pitts*, 411 U.S. 138, 143 (1973). Here, however, Plaintiffs' only claim raises a pure question of constitutional law, and Defendants' arguments for dismissal are also purely legal. Accordingly, there is no need for an administrative record, and Defendants do not intend to submit

is psychoactive ('mood altering') and can provide pleasurable effects," and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." *Id.* E-cigarettes can deliver as much nicotine as conventional cigarettes—sometimes more. Deeming Rule, 81 Fed. Reg. at 29,031.

2. Health Hazards of Nicotine: Nicotine is toxic at high doses, and can harm adolescents, pregnant women, and fetuses. *Id.* at 29,033. Nicotine exposure during pregnancy "contribut[es] to multiple adverse outcomes such as preterm delivery and stillbirth," and "has lasting adverse consequences for [fetal] brain development." HHS, Office of the Surgeon Gen., *The Health Consequences of Smoking—50 Years of Progress* 126 (2014) (JA 216). Nicotine exposure during adolescence "may have lasting adverse consequences for brain development." *Id.* Ingesting or touching e-liquids can cause nicotine poisoning, which can be fatal. Deeming Rule, 81 Fed. Reg. at 29,032 (1,700 e-liquid exposures reported to U.S. poison control centers from 2010-2013, mostly involving young children); *id.* at 29,036 (toddler died after ingesting liquid nicotine).

3. Health Hazards of Other Ingredients: What information is available about the ingredients found in e-liquids shows that many present known health concerns. *Id.* at 29,029 (study found that 74% of eliquids contained substances posing known inhalation risks); *id.* (study found that many e-liquids contain chemicals that can cause respiratory irritation and airway constriction); *id.* (study found that some e-liquids contain chemical that is highly toxic to human cells in lab tests).

4. Variability in Content and Concentration: Among e-liquids, there is "significant . . . variability between labeled content and concentration and actual content and concentration." *Id.* at 28,984; *see also id.* at 29,034 (study found that some e-liquids claiming to be nicotine-free actually had high levels of nicotine); *id.* (study found that actual nicotine level of 65% of e-liquids deviated by more than 10% from concentration printed on labels).

5. Variability in Nicotine Delivery: Among e-cigarette devices, variations in design and performance affect the amount of chemicals actually inhaled by users. Nicotine delivery "varies widely depending on product characteristics, user puffing behavior[,] and nicotine solution concentration, leaving smokers unaware of the nicotine levels they are receiving." *Id.* at 29,032. Devices that "heat[] e-liquids to higher temperatures . . . may result in nicotine delivery that is actually higher than that of a conventional cigarette." *Id.* at 29,031.

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one (at least at this time). Nevertheless, to provide context, Defendants have cited materials from the administrative record for the deeming rule, to which other courts have properly limited their review. *See, e.g.*, *Nicopure Labs. LLC v. FDA*, No. 16-878 (D.D.C.) (minute order of Aug. 2, 2016). Rather than burden this Court's docket with those voluminous materials, however, Defendants will occasionally cite here to the Joint Appendix publicly filed in *Moose Jooce* (a First Amendment and Appointments Clause challenge to the deeming rule), which contains some pertinent excerpts. None of Defendants' arguments for dismissal in this case require the Court to opine on the factual accuracy of that material.

6. Variability in Delivery of Other Toxic Chemicals: Design variations affect the delivery of other toxic chemicals. The solvents in e-liquids are chosen to create aerosols simulating conventional cigarette smoke, but when vaporized at certain voltages, they can produce some of the same harmful byproducts as conventional cigarettes, sometimes at higher levels. Cheng (2014) at ii13 (JA 231). Devices operated at higher voltages deliver more formaldehyde, a known carcinogen, than conventional cigarettes. Deeming Rule, 81 Fed. Reg. at 29,031. Toxic heavy metals, silicates, and other compounds can also be transferred from e-cigarette parts into the inhaled aerosol. *Id.* at 29,015.

7. Risks of Batteries: The batteries and other components in e-cigarettes pose their own health and safety risks. Serious injuries like facial burns and lost teeth have been attributed to exploding batteries. 81 Fed. Reg. at 29,035. The U.S. Fire Administration found that the shape of e-cigarettes makes them more likely to shoot off like "flaming rockets" when a battery fails. U.S. Fire Administration, Electronic Cigarette Fires and Explosions 1 (2014) (25 media reports of e-cigarette explosions or fires from 2009-2014), *available at* https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf. The U.S. Department of Transportation banned e-cigarettes from checked luggage because they "can overheat and cause fires when the heating element is accidentally activated or turned on." 80 Fed. Reg. 66,817, 66,817-66,818 (Oct. 30, 2015).

8. Health Hazards to Nonusers: E-cigarettes, just like conventional cigarettes, may harm nonusers. Secondhand aerosol contains nicotine, which is absorbed through passive exposure, with one study showing levels comparable to passive smokers of conventional cigarettes. *See* Deeming Rule, 81 Fed. Reg. at 29,031-29,032 (studies show that "secondhand e-cigarette aerosols have been found to contain at least 10 chemicals known to cause cancer, birth defects, or other reproductive harm").

9. Marketing to Youth: E-cigarette advertising specifically targets youth. In addition to using flavors both engineered and branded to appeal to youth, e-cigarette companies have aired ads during programs with high youth viewership, like the Super Bowl, the Academy Awards, and on ESPN and Comedy Central. Durbin et al. (2014) at 16 (JA 223). And their ads have often used celebrity endorsements and depict e-cigarettes as glamorous, rebellious, sexy, and masculine. *Id.* at 17 (JA 224); Grana & Ling (2014) at 399 (JA 233).

It remains unclear whether e-cigarettes help smokers quit in meaningful numbers. Although there is "some indication that such products may have the potential to help some individual users to quit using combusted tobacco products or to reduce their use of such products," "other evidence is to the contrary," and "some systematic reviews of available evidence indicate that there is currently

insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device." Deeming Rule, 81 Fed. Reg. at 29,037. Indeed, e-cigarettes may actually *inhibit* quitting conventional cigarettes, as "adult smokers who begin to use e-cigarettes seldom completely quit combustible products," Primack et al. (2015) at 1019 (JA 240)—a particularly troubling prospect given the substantial risks of even light or intermittent smoking. As the Surgeon General has reported, "the strongest determinant of risk for many diseases (*e.g.*, lung cancer) caused by tobacco use is the duration"—not the quantity—"of smoking." HHS, Office of the Surgeon Gen., *How Tobacco Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease* 78 (2010) (JA 210). The U.S. Preventive Services Task Force, an independent, volunteer panel of national experts, has concluded "that available data on the use of [e-cigarettes] for smoking cessation are quite limited and suggest no benefit among smokers intending to quit." JA 236.

The extent to which e-cigarettes are a "gateway" to the use of other tobacco products, like cigarettes, is also uncertain. Some evidence suggests "youth may initiate tobacco use with [e-cigarettes], become addicted [to nicotine], and then dual use or move on to traditional tobacco products." Deeming Rule, 81 Fed. Reg. at 29,040-41 (one-year study of initially nonsmoking youth and young adults showed that 68.8% of e-cigarette users progressed toward smoking (*i.e.*, either tried conventional cigarettes or indicated that they might), compared to just 18.9% of nonusers).

D. FDA issues the deeming rule, subjecting e-cigarettes to meaningful regulatory scrutiny for the first time.

As mentioned above, Congress made the Tobacco Control Act applicable to four named categories of tobacco products—"all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—but also "to any other tobacco products that the Secretary [of Health and Human Services] by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b). Accordingly, FDA's statutory rulemaking authority explicitly includes the authority to issue a

"regulation deem[ing]" "any other tobacco products" to be subject to the requirements of the TCA (including premarket review). *Id.*

Congress defined the term "tobacco product" with specificity: as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1).[9] In 2010, the D.C. Circuit held that e-cigarettes meet this definition—nicotine, after all, is "derived from tobacco," *id.*—and thus that "the FDA has authority under the [TCA] to regulate electronic cigarettes, enabling it to mitigate or perhaps extinguish any harm to public health." *Sottera*, 627 F.3d at 898; *see also Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 381 (D.D.C. 2017) (holding that the "FDA [also] has the statutory authority to regulate open-system vaping devices"), *appeal pending on other grounds*, No. 17-5196 (D.C. Cir. argued Sept. 11, 2018). Plaintiffs in this case appear not to dispute that their e-cigarette products fall within the statutory definition of a "tobacco product" in 21 U.S.C. § 321(rr)(1).

The FDA concluded in 2016, based on the data summarized above, that the known risks posed by e-cigarettes warranted increased regulatory scrutiny. As the FDA explained, even if e-cigarettes were ultimately proven to be a net benefit to public health, FDA oversight of those products would benefit public health even further. 81 Fed. Reg. at 28,984. Accordingly, on May 10, 2016, FDA published the final "deeming rule," which deems e-cigarettes (as well as cigars, pipe tobacco, and other tobacco products, except accessories) to be "new tobacco products" subject to the TCA. *Id.* at 28,974-75.

[9] Congress also specified: "[t]he term 'tobacco product' does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title." 21 U.S.C. § 321(rr)(2). Congress also excepted "tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives." *Id.* § 387a(2)(A).

As a result of the combination of the deeming rule and the Tobacco Control Act, the e-cigarette industry became subject to meaningful FDA scrutiny for the first time in the summer of 2016. Thus, without the deeming rule, the FDA could not require e-cigarettes and e-liquids to have accurate labels. It could not require warnings about their addictive potential. It could not require that toxic and carcinogenic chemicals be reduced or eliminated. It could not verify that purportedly "modified risk" products do, in fact, reduce risk. And absent the deeming rule, there would no longer be any federal prohibition on the sale of e-cigarettes to minors, *see* 21 C.F.R. § 1140.14(b)(1) ("No retailer may sell covered tobacco products to any person younger than 18 years of age.") (citing Deeming Rule, 81 Fed. Reg. at 29,103; *see also* 21 U.S.C. § 387f(d)(1) ("The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product . . . if the Secretary determines that such regulation would be appropriate for the protection of the public health.")).

E. The FDA exercises its discretion to defer enforcement of certain requirements.

Once the deeming rule took effect in August 2016, the newly regulated products immediately became subject to the requirements of the FDCA (as amended by the TCA). Accordingly, in an exercise of its enforcement discretion, FDA simultaneously announced "compliance periods" during which the FDA did not intend to bring enforcement actions against manufacturers under certain of the TCA's provisions. 81 Fed. Reg. at 29,003-15 & tbls. 2-3. For products on the market as of August 8, 2016, FDA intended to defer enforcement of the TCA's premarket review requirements for two years, until August 2018, for the submission of PMTAs (the type of premarket application expected for ENDS products) and for up to one additional year, until August 2019, while any timely submitted applications were reviewed by the FDA. *Id.* at 29,010-11. The FDA noted, however, that "[a]s with any such policy, the Agency will review and revise this policy as appropriate." *Id.* at 29,008.

In July 2017, FDA announced a "new comprehensive plan" for the regulation of tobacco products, which would place "nicotine, and the issue of addiction, at the center of [its] tobacco regulation efforts."[10] July 27, 2017 Press Release. In particular, the agency set a new goal of "lowering nicotine levels in combustible cigarettes to non-addictive levels." *Id.* The agency also explained that, while it was pursuing these goals, it also wished to encourage "innovations that have the potential to make a notable public health difference," July 27, 2017 Press Release. As part of that effort, FDA explained that it intended to further defer enforcement of the TCA's premarket review provisions for products already on the market as of August 8, 2016, when the deeming rule took effect.[11] Under this "new compliance policy," the compliance period for seeking premarket authorization was extended to August 2022 for noncombustible products (like most e-cigarettes). 2017 Guidance at 3. During these periods, FDA stated that it did "not intend to enforce" the TCA's premarket review provisions "as a matter of enforcement discretion." 2017 Guidance at 4. The 2017 Guidance explicitly warned that it merely "represent[ed] the current thinking of the [FDA] on this topic," and "does not establish any rights for any person and is not binding on [the] FDA or the public." 2017 Guidance at 1.

On March 27, 2018, the American Academy of Pediatrics filed suit in the U.S. District Court for the District of Maryland, arguing that the FDA's 2017 Guidance was unlawful. Although FDA vigorously defended that lawsuit, ultimately, on May 15, 2019, the court vacated the 2017 Guidance. *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019) (*AAP*). Accordingly, the FDA is now under a court-ordered obligation to "require that, for new tobacco products on the market as of

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[10] FDA, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (July 27, 2017) ("July 27, 2017 Press Release") at 1, *available at* https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

[11] FDA, *Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (Aug. 2017) ("2017 Guidance"), *available at* https://www.fda.gov/media/105346/download.

[] August 8, 2016 . . . applications for marketing orders must be filed within 10 months of" the Maryland court's order—*i.e.*, by May 12, 2020. *AAP*, 2019 WL 3067492, at *7 (D. Md. July 12, 2019). *AAP* is now before the Fourth Circuit.

F. The FDA continues to combat the epidemic of youth vaping.

Notwithstanding various industry challenges to the FDA's exercise of its statutory authority to regulate tobacco products, the FDA continues to combat the epidemic of youth vaping, which has surged in recent years. The agency has issued more than 10,000 warning letters and more than 1,400 civil penalties to both online and brick-and-mortar retailers of e-cigarette products who sell to minors.[12] The FDA has also issued warning letters to manufacturers who produce e-liquid products that resemble kid-friendly juice boxes, cereal, and candy, and with respect to online posts by social media influencers marketing youth-friendly flavored e-liquids.[13] Recently, the FDA issued a warning letter to JUUL (the world's largest manufacturer of e-cigarettes) for marketing unauthorized "modified risk" tobacco products by engaging in inappropriate labeling, advertising, and other activities directed to consumers—including a presentation to youth at a school.[14] None of those efforts to enforce the Tobacco Control Act would be possible without the deeming rule.

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[12] Testimony of Acting Commissioner of Food and Drugs Norman E. Sharpless, M.D., *FDA Regulations of Electronic Nicotine Delivery Systems and Investigation of Vaping Illnesses* (Sept. 25, 2019), *available at* https://www.fda.gov/news-events/congressional-testimony/fda-regulation-electronic-nicotine-delivery-systems-and-investigation-vaping-illnesses-09252019.

[13] FDA, *FDA, FTC, take action against companies misleading kids with e-liquids that resemble children's juice boxes, candies and cookies* (Apr. 30, 2018), *available at* https://www.fda.gov/news-events/press-announcements/fda-ftc-take-action-against-companies-misleading-kids-e-liquids-resemble-childrens-juice-boxes; FDA, *FDA, FTC take action to protect kids by citing four firms that make, sell flavored e-liquids for violations related to online posts by social media influencers on their behalf* (June 7, 2019), *available at* https://www.fda.gov/news-events/press-announcements/fda-ftc-take-action-protect-kids-citing-four-firms-make-sell-flavored-e-liquids-violations-related.

[14] FDA, *FDA warns JUUL Labs for marketing unauthorized modified risk tobacco products, including in outreach to youth* (Sept. 9, 2019), *available at* https://www.fda.gov/news-events/press-

The FDA has made clear that it "will not stand idly by as these products become an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth."[15] Thus, while the *AAP* court ordered premarket applications for all newly deemed products to be filed by May 12, 2020, in the meantime the FDA has stated its intent to finalize and issue a new compliance policy (originally published in draft form in March 2019[16]) that would prioritize the agency's enforcement of the premarket authorization requirements for flavored e-cigarettes that appeal to youth.[17] As of the date of this filing, no such policy has been finalized or issued.

G. More than three years after it went into effect, Plaintiffs file this lawsuit challenging the deeming rule.

Plaintiff United States Vaping Association ("USVA") is a trade association representing the e-cigarette industry. Compl., ECF No. 1 ¶ 9. Plaintiff Big Time Vapes is a retailer and manufacturer of e-cigarettes. *Id.* ¶ 8. Plaintiffs claim that Big Time Vapes and USVA's members have been complying with the TCA and the deeming rule since that rule went into effect in the summer of 2016. *See* Pls.' Mem. in Supp. of Mot. for Prelim. Inj., at 12, ECF No. 17 ("Pls.' Br."). If that is true, then they long ago registered with the FDA, 21 U.S.C. § 387e(b), filed a list of all their tobacco products,

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announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth.

[15] FDA, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019), *available at* https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[16] *See* FDA, Draft Guidance for Industry, *Modifications to Compliance Policy for Certain Deemed Tobacco Products* (March 2019), *available at* https://www.fda.gov/media/121384/download.

[17] *Sounding the Alarm: The Public Health Threats of E-Cigarettes: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce, 116th Cong.* (Sept. 25, 2019) (prepared remarks of Acting Comm'r. of Food & Drugs Norman E. Sharpless, M.D.), *available at* https://www.fda.gov/news-events/press-announcements/remarks-preparedtestimony-us-house-energy-and-commerce-subcommittee-fda-regulation-electronic.

id. § 387e(i), and disclosed the identity and quantity of all ingredients in each product, *id.* § 387d(a)(1)-(2), among other things.

Nevertheless, more than three years *after* the deeming rule went into effect, Plaintiffs filed this constitutional challenge, seeking to invalidate under the nondelegation doctrine the TCA's provision delegating "deem[ing]" authority to the Secretary, *see* 21 U.S.C. § 387a(b), as well as the deeming rule promulgated pursuant to that authority. Compl., ECF No. 1, ¶¶ 52-65. Almost two months after filing their complaint, on October 12, 2019, Plaintiffs moved for a preliminary injunction, asking the Court to "enjoin Defendants from exercising any authority over any 'tobacco products' deemed to be subject to the TCA pursuant to 21 U.S.C. § 387a(b), including, but not limited to, the current Deeming Rule and any enforcement of same." Pls.' Br. at 53.

LEGAL STANDARDS

To survive a motion to dismiss for failure to state a claim, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In reviewing a motion to dismiss, courts may consider the complaint, "documents either attached to or incorporated in the complaint," and "matters of which they may take judicial notice." *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996). In addition, "[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Causey v. Sewell Cadillac-Chevrolet, Inc.*, 394 F.3d 285, 288 (5th Cir. 2004).

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter*, 555 U.S. at 24. "The Fifth Circuit frequently cautions that . . . 'the decision to grant a preliminary injunction is to be treated as the exception rather than the rule.'" *Matrix Partners VIII, LLP v. Nat. Res. Recovery, Inc.*, No. 1:08-cv-547, 2009 WL 175132, at *6 (E.D. Tex. Jan. 23, 2009) (alteration omitted) (quoting

House the Homeless, Inc. v. Widnall, 94 F.3d 176, 180 (5th Cir. 1996)). The party seeking a preliminary injunction thus bears the burden to show: "(1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, *and* (4) that the grant of an injunction will not disserve the public interest." *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016) (emphasis added). Due to its "extraordinary" nature, no preliminary-injunction motion should be "granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements." *Id.* at 221 (citation and internal punctuation omitted). In practice, however, the third and fourth factors tend to "merge when the Government is the opposing party," *Nken v. Holder*, 556 U.S. 418, 435 (2009), into consideration of the public interest.

ARGUMENT

The Supreme Court has not invalidated a statute on nondelegation grounds since 1935, and it is now well-settled that, although Congress may not delegate away its "legislative" powers, it may confer discretion on the Executive Branch to implement and enforce federal law, so long as it provides "an intelligible principle." *J.W. Hampton*, 276 U.S. at 409. A delegation passes muster under that lenient standard "if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *American Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946). The Court has thus upheld numerous delegations of authority across a wide range of substantive areas. There is nothing sufficiently novel or unprecedented about the Tobacco Control Act that would take it outside the bounds of this consistent line of precedent. On that basis alone, the complaint may be dismissed in its entirety for failure to state a claim, and Plaintiffs' motion for a preliminary injunction may be denied as moot, or for failure to demonstrate any "substantial

likelihood" of success on the merits. Plaintiffs have also failed to carry their burden on the other preliminary-injunction factors, although the Court need not reach those issues.

I. THE TOBACCO CONTROL ACT DELEGATES NON-LEGISLATIVE POWER TO THE EXECUTIVE CONSISTENT WITH BINDING PRECEDENT.

The Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." Art. I, § 1. The Supreme Court has explained that "[t]his text permits no delegation of those powers." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 472 (2001). But the Court "ha[s] recognized, however, that the separation-of-powers principle, and the nondelegation doctrine in particular, do not prevent Congress from obtaining the assistance of its coordinate Branches." *Mistretta v. United States*, 488 U.S. 361, 372 (1989). Accordingly, Congress may confer discretion on the Executive to implement and enforce the laws so long as it supplies an "intelligible principle" informing the agency's exercise of that discretion. *Id.* (quoting *J.W. Hampton*, 276 U.S. at 409). The Tobacco Control Act, interpreted as a whole, plainly satisfies that lenient standard: by delegating narrow authority to the Executive Branch to implement one statutory term—"tobacco product"—that Congress already defined with precision.

A. Congress may delegate discretion to the Executive if it supplies an intelligible principle: by defining the general policy, the official to whom authority is delegated, and the limits of the delegated authority.

The Constitution does not "deny[ ] to the Congress the necessary resources of flexibility and practicality . . . to perform its function." *Yakus v. United States*, 321 U.S. 414, 425 (1944) (citation omitted). Accordingly, the Supreme Court "ha[s] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law.'" *American Trucking*, 531 U.S. at 474-475 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)). The Supreme Court's precedents likewise make clear that "Congress is not confined to that method of executing its policy which involves the least possible delegation of discretion to

administrative officers." *Yakus*, 321 U.S. at 425-426. Instead, the "extent and character of th[e] assistance" Congress may seek from another branch in a particular context "must be fixed according to common sense and the inherent necessities of the governmental co-ordination" at issue, *J.W. Hampton*, 276 U.S. at 406—matters Congress is best positioned to assess. *See Mistretta*, 488 U.S. at 372.

Consistent with that understanding, "[f]rom the beginning of the Government," Congress has enacted, and the Supreme Court has upheld, statutes "conferring upon executive officers power to make rules and regulations—not for the government of their departments, but for administering the laws which did govern." *United States v. Grimaud*, 220 U.S. 506, 517 (1911). As early as the Washington Administration, Congress enacted broad delegations that went untouched by the Supreme Court. For example, the First Congress delegated authority to the Executive to license and regulate trade with Indian tribes, Act of July 22, 1790, ch. 33, 1 Stat. 137; to issue patents, Act of Apr. 10, 1790, ch. 7, 1 Stat. 109; and to regulate military-disability pay, Act of Apr. 30, 1790, ch. 10, § 11, 1 Stat. 119. Early Congresses also enacted a series of statutes that delegated to the President the power to impose or lift trade sanctions and tariffs. *Marshall Field & Co. v. Clark*, 143 U.S. 649, 683-689 (1892).

The Supreme Court rejected a nondelegation challenge to one such statute in 1813. *See The Cargo of the Brig Aurora v. United States*, 11 U.S. (7 Cranch) 382 (1813). The Non-Intercourse Act of March 1, 1809, ch. 24, 2 Stat. 528, authorized an embargo of British and French ships from American ports, but Congress made the embargo contingent on a presidential proclamation applying it to Great Britain or France or both. *See Marshall Field*, 143 U.S. at 682; Act of May 1, 1810, ch. 39, § 4, 2 Stat. 606. President Madison issued such a proclamation as to Great Britain. *See Marshall Field*, 143 U.S. at 682. The *Aurora*, a British ship, then docked in New Orleans, and the government seized its cargo under the Act. *The Brig Aurora*, 11 U.S. (7 Cranch) at 387-388. The cargo's owner sued, contending that "Congress could not transfer the legislative power to the President" and that "[t]o make the

revival of a law depend upon the President's proclamation, is to give to that proclamation the force of law." *Id.* at 386 (argument of counsel). The Supreme Court rejected that challenge, concluding that it could "see no sufficient reason[] why the legislature should not exercise its discretion in reviving the [Act], either expressly or conditionally, as their judgment should direct." *Id.* at 388.

Congress enacted similar statutes throughout the late 1700s and the 1800s. *See Marshall Field*, 143 U.S. at 683-689. It does not appear that the Supreme Court addressed another challenge to a congressional delegation to the Executive Branch until 1892, when the Court in *Marshall Field* again upheld a statute making the applicability (or lack thereof) of certain tariffs contingent on country-specific Presidential determinations. *Id.* at 681-694. The Court explained that *The Brig Aurora* and the history of "so many acts of Congress," which "embrac[ed] almost the entire period of our national existence," foreclosed the challengers' nondelegation argument. *Id.* at 691.

Applying the same principles, the Court rejected nondelegation challenges to a number of other statutes through the early 1900s. For example, in *In re Kollock*, 165 U.S. 526 (1897), the Court upheld a statute that authorized the Commissioner of Internal Revenue to issue regulations defining packaging requirements for oleomargarine. *Id.* at 532-533. In *Union Bridge Co. v. United States*, 204 U.S. 364, 387 (1907), the Court sustained a statute that authorized the Secretary of War to order modifications to any bridge he found was "an unreasonable obstruction to the free navigation of" a navigable waterway. *Id.* at 366 (statement of case) (citation omitted); *see id.* at 386-388 (upholding statute and explaining that a "denial to Congress of the right, under the Constitution, to delegate the power to determine some fact or the state of things upon which the enforcement of its enactment depends, would be 'to stop the wheels of government' and bring about confusion, if not paralysis, in the conduct of the public business"). And *Grimaud* rejected a nondelegation challenge to a statute that

authorized the Secretary of Agriculture to set rules for grazing in public forests in order "to regulate their occupancy and use, and to preserve the forests thereon from destruction." 220 U.S. at 515-517.

In 1928, the Supreme Court summarized its decisions as providing that "legislative action is not a forbidden delegation of legislative power," so long as "Congress shall lay down by legislative act an intelligible principle to which the person or body authorized" to exercise the delegated authority "is directed to conform." *J.W. Hampton*, 276 U.S. at 409. Nearly 20 years later, the Court clarified that a delegation is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *American Power & Light*, 329 U.S. at 105. Applying those principles, the Supreme Court has upheld nearly every delegation it has confronted, including delegations:

- To the President to set and adjust tariffs as needed to "equalize the . . . differences in costs of production" between foreign and domestic goods. *J.W. Hampton*, 276 U.S. at 401 (citation omitted); *see id.* at 407-411.

- To the Federal Communication Commission to regulate broadcast licensing "as public interest, convenience, or necessity" requires. *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 225-226 (1943).

- To the Federal Power Commission to determine "just and reasonable" rates for wholesale sales of natural gas. *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 600 (1944).

- To the Price Administrator to fix commodity prices that would be "fair and equitable" and would "effectuate the purposes of th[e] [Emergency Price Control Act of 1942, ch. 26, 56 Stat. 23]"—the violation of which resulted in criminal sanctions. *Yakus*, 321 U.S. at 420 (citation omitted); *see id.* at 425-427.

- To the Securities and Exchange Commission to prevent unfair or inequitable distribution of voting power among security holders. *American Power & Light*, 329 U.S. at 105.

- To the Secretary of War to determine and recover "excessive profits" from military contractors. *Lichter v. United States*, 334 U.S. 742, 785-786 (1948).

- To the Federal Home Loan Administration to make "rules and regulations . . . for the reorganization, consolidation, merger, or liquidation of [savings-and-loan] associations." *Fahey v. Mallonee*, 332 U.S. 245, 247, 249-250 (1947) (citation omitted).

- To the Sentencing Commission to promulgate (then-binding) Sentencing Guidelines establishing the permissible sentences for federal crimes. *Mistretta*, 488 U.S. at 374-377.
- To the Attorney General to designate controlled substances on a temporary basis, resulting in criminal penalties for unauthorized manufacture, possession, or distribution of such substances. *Touby v. United States*, 500 U.S. 160, 165-167 (1991).
- To the President to identify aggravating factors used to impose the death penalty in courts martial. *Loving v. United States*, 517 U.S. 748, 771-774 (1996).
- To the Environmental Protection Agency to set nationwide air-quality standards limiting pollution to the level required "to protect the public health." *American Trucking*, 531 U.S. at 472 (quoting 42 U.S.C. § 7409(b)(1)); *see id.* at 472-476.

In our Nation's history, only twice has the Supreme Court found that a delegation exceeded Congress's authority. *American Trucking*, 531 U.S. at 474. In 1935, the Court concluded that two provisions of the National Industrial Recovery Act (Recovery Act), ch. 90, 48 Stat. 195, contained "excessive delegations" because Congress "failed to articulate *any* policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power." *Mistretta*, 488 U.S. at 373 & n.7 (emphasis added). The Court held those provisions invalid because "one . . . provided literally no guidance for the exercise of discretion, and the other . . . conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *American Trucking*, 531 U.S. at 474 (citation omitted). But since 1935, the Supreme Court has "upheld, again without deviation, Congress' ability to delegate power under broad standards." *Mistretta*, 488 U.S. at 373. Put differently, outside of one statute—enacted at the height of the expansion of federal power during the New Deal—no nondelegation argument has ever succeeded.

The Supreme Court rejected its most recent nondelegation challenge this past June, upholding a provision in the Sex Offender Registration and Notification Act (SORNA) that delegated to the Attorney General authority to decide whether and under what circumstances that statute's registration requirements (and its accompanying criminal penalties) would apply to sex offenders convicted *before*

the statute's enactment, holding that "[t]hat delegation easily passes constitutional muster." *Gundy*, 139 S. Ct. at 2121 (plurality op.); *see also id.* at 2130-2131 (Alito, J., concurring in the judgment). Accordingly, the precedent that binds this Court remains settled: Congress may delegate discretionary authority to the Executive Branch—even pursuant to "extraordinarily capacious standards," *id.* at 2131 (Alito, J., concurring in the judgment)—without running afoul of the Constitution.

B. The Tobacco Control Act comports with Supreme Court precedent because the statute as a whole supplies an intelligible principle.

Congress may delegate to the Executive so long as it "lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform." *J.W. Hampton*, 276 U.S. at 409. Under that standard, a delegation is "constitutionally sufficient if Congress clearly delineates" (1) "the general policy" to be pursued, (2) "the public agency which is to apply it," and (3) "the boundaries of th[e] delegated authority." *American Power & Light*, 329 U.S. at 105. The deeming authority in the Tobacco Control Act, 21 U.S.C. § 387a(b)—particularly when interpreted in the context of the statute as a whole, with an eye to Congress's purpose—satisfies these requirements.

i. Congress identified the agency to whom authority is delegated.

Plaintiffs do not directly address the *American Power & Light* standard, but they do not appear to dispute that Congress appropriately identified the recipient of the relevant delegated authority. Nor could they: the FDCA, as amended by the Tobacco Control Act, unquestionably identifies "the public agency which is to apply" the relevant federal policy, *American Power & Light*, 329 U.S. at 105, by expressly vesting discretion in the Secretary of Health and Human Services, *see* 21 U.S.C. § 387a(b), and in his subordinates at the Food and Drug Administration, *id.* § 393(d)(2).[18]

[18] Plaintiffs appear not to challenge any of the internal delegations of authority *within* HHS or FDA; they challenge only the original, top-level delegation from Congress to the Executive Branch in 21 U.S.C. § 387a(b). *See* Pls.' Br. at 11 n.3 (citing without any apparent disapproval sub-delegations to

ii. Congress identified the limits of the delegated authority.

a. Congress also "clearly delineate[d] . . . the boundaries of th[e] delegated authority." *American Power & Light*, 329 U.S. at 105. At the outset, Congress itself "made virtually every legislative determination" in the Tobacco Control Act, "which has the effect of constricting" the agency's remaining "discretion to a narrow and defined category." *Whaley*, 577 F.3d at 264 (quoting in a parenthetical *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009)). Congress defined "tobacco product" with precision: as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1); *see also supra* at 13 n.9 (further limitations). Congress specified the requirements for disclosure of ingredients, 21 U.S.C. § 387d(a)(1)-(2), product labels, *id.* § 387c, warnings, *id.* § 387f(d)(1)-(2); 15 U.S.C. § 4402(a)(1), and so-called "modified risk" claims, 21 U.S.C. § 387k. Congress required manufacturers to register with the FDA, *id.* § 387e(b), and list their products, *id.* § 387e(i). Congress required premarket authorization, *id.* § 387j(a)(1)-(2), and specified in detail each of three separate procedural pathways, *id.* § 387j(b)-(c) (premarket tobacco applications); *id.* §§ 387j(a)(2)(A)(i), 387e(j)(1) (substantial equivalence reports); *id.* §§ 387j(a)(2)(A)(ii), 387e(j)(3) (substantial equivalence exemption). And Congress placed specific restrictions on industry marketing practices, *id.* § 387a-1(a), and largely banned free samples, *see* Pub. L. No. 111-31, § 102(a)(2)(G).

Having addressed all of those matters in the statute itself, Congress then (1) specified that these requirements were to be made applicable to a defined subset of listed "tobacco products" (*i.e.*,

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and within FDA). Again, nor could they. *See, e.g.*, *Touby*, 500 U.S. at 169 (upholding the Attorney General's re-delegation of authority to the Drug Enforcement Administration, holding that such sub-delegation is permissible "unless a specific limitation" on doing so "appears elsewhere in the statute"). Congress has not only failed to prohibit re-delegation of the relevant aspects of the Secretary's authority to the FDA, but has in fact expressly authorized it. *See* 21 U.S.C. § 393(d)(2).

"cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"), and (2) delegated to the Executive the authority to "by regulation deem[]" "any other tobacco products" "to be subject to this subchapter" (*i.e.*, other "tobacco products" not listed in the preceding clause, but that still meet the definition in 21 U.S.C. § 321(rr)). *See id.* § 387a(b). FDA thus "is left only with the discretion to determine whether" the requirements "articulated by the legislature apply" to "a narrow and defined category," *Ambert*, 561 F.3d at 1214, of "tobacco products" defined in 21 U.S.C. § 321(rr).

b. In *United States v. Womack*, 654 F.2d 1034 (5th Cir. 1981), the Fifth Circuit rejected a nondelegation challenge to a statute that, just like the Tobacco Control Act, imposed fixed statutory requirements with respect to a congressionally defined category, but gave the Executive Branch discretion to determine the applicability of the statute to products falling within that category—holding that the statutory definition, standing alone, provided the requisite intelligible principle. In *Womack*, the defendant "appeal[ed] from his conviction . . . on six counts of knowingly engaging in the business of manufacturing explosive materials without a license in violation of 18 U.S.C. § 842(a)(1)," *id.* at 1036, a statute that defined "explosive materials" and "explosives" as follows:

> **(c)** "Explosive materials" means explosives, blasting agents, and detonators.
>
> **(d)** . . . "explosives" means any chemical compound mixture, or device, the primary or common purpose of which is to function by explosion; the term includes, but is not limited to, dynamite and other high explosives, black powder, pellet powder, initiating explosives, detonators, safety fuses, squibs, detonating cord, igniter cord, and igniters. The Secretary [of the Treasury] shall publish and revise at least annually in the Federal Register a list of these and any additional explosives which he determines to be within the coverage of this chapter. . . .

Id. at 1036 n.2 (quoting 18 U.S.C. § 841 (1976)). "The explosive materials manufactured by Womack were M-80's, which have the general appearance of oversized firecrackers," *id.* at 1036, and which—at least according to a list published annually by the Secretary of the Treasury, under the authority delegated in 18 U.S.C. § 841—qualified as "explosives," *id.* at 1039. Womack argued "that 18 U.S.C.

§ 841, which defines 'explosive materials' and 'explosives' and further authorizes the Secretary of the Treasury to list additional explosives, unconstitutionally delegates legislative power." *Id.* at 1036.

The Fifth Circuit affirmed the conviction, "reject[ing] Womack's assertion that [the statute] . . . does not provide the Secretary of the Treasury with adequate standards or safeguards to control the listing of explosives." *Id.* at 1038. It explained:

> [The statute] carefully defines the term "explosives" as "any chemical compound mixture, or device, the primary or common purpose of which is to function by explosion" and an illustrative list of subject explosives is provided. 18 U.S.C. § 841(d). The Treasury Secretary listed as an explosive material the substance "explosive perchlorate mixture." The standards are sufficiently definite given the complexity and nature of the area to which the legislation is directed.

Id.. The same is true of the Tobacco Control Act: (1) it "carefully defines the term" (*i.e.*, "tobacco product," *see* 21 U.S.C. § 321(rr)); (2) it provides "an illustrative list of subject" tobacco products (*i.e.*, "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," *id.*); and (3) its "standards are sufficiently definite given the complexity and nature of the area to which legislation is directed" (*e.g.*, a new, potentially harmful technology for inhaling an aerosolized vapor of mixed chemicals, including nicotine derived from tobacco). Although it does not appear in Plaintiffs' brief, *Womack* is on all fours with this case.

c. Although this Court (bound as it is by existing precedent) need not wade into the debate surrounding the future of the nondelegation doctrine, the narrow delegation at issue here is largely outside the scope of that debate. Skeptics of the existing, forgiving conception of the doctrine are concerned about what they perceive to be Congress's increasing habit of delegating away authority to fashion substantive rules, or authorizing Executive agencies to write detailed codes of conduct governing private behavior. *See, e.g.*, *Gundy*, 139 S. Ct. at 2131 (Gorsuch, J. dissenting) (arguing in dissent that the Court had upheld a statute that "purports to endow the nation's chief prosecutor with the power to write his own criminal code governing the lives of a half-million citizens"). Plaintiffs

appear to share that concern, stating in their complaint that "[t]he essence of 'legislative power' is the power to set out the policy by which private conduct is to be governed." Compl. ¶ 56.

But the challenged statutory provision (21 U.S.C. § 387a(b)) does not delegate to FDA the authority to fashion substantive rules. Instead, the statute *itself* imposes an array of detailed requirements on a subset of listed tobacco products, *see supra* at 5-7, 26, all of which meet the definition of "tobacco product" that Congress provided in 21 U.S.C. § 321(rr). In section 387a(b), Congress delegated only the narrow authority to identify *other* subsets of the broader statutory category of "tobacco product" to *also* be covered by the requirements of the TCA—requirements drafted by *Congress*—as long as any deemed "tobacco products" fall within the definition that Congress supplied in 21 U.S.C. § 321(rr). So any concern about agencies writing substantive laws (or defining crimes) of the sort at issue in *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), or *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935) (or in *Gundy*, according to the dissenting justices) is inapplicable.

To be sure, as authorized by a century of precedent, *other* statutory provisions do provide FDA with general authority to issue substantive regulations on certain subjects.[19] But Plaintiffs do not challenge any of those provisions here—their claim is limited to the "deeming" authority in 21 U.S.C. § 387a(b). *See* Compl., Prayer ¶ 1 (asking the Court to "Declare Section 901 of the TCA, *codified at* 21 U.S.C. § 387a, to be in violation of Article I of the Constitution of the United States, and, consequently, the Deeming Rule promulgated under its authority to be invalid."). That provision is not only consistent with existing precedent that binds this Court, it should also raise little concern even with those who disfavor that existing precedent.

[19] *See, e.g.*, 21 U.S.C. § 387f(d)(1) (authorizing the Secretary of Health and Human Services to "require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health").

iii. Congress identified the general policy it intended the agency to pursue.

As for the remaining *American Power & Light* factor, Plaintiffs also appear to dispute that Congress has identified the "general policy" for the agency to pursue. 329 U.S. at 105. But Plaintiffs' treatment of the deeming authority in 21 U.S.C. § 387a(b) as a barren grant of authority bereft of any congressional guidance ignores the totality of the statutory text, Congress's expressly stated purposes, and critical context—all contrary to the teachings of binding precedent.

a. In a nondelegation challenge, "[t]he standards of the statute are not to be tested in isolation but must derive meaningful content from the purpose of the statute and its factual background and the statutory context in which the standards appear." *Womack*, 654 F.2d at 1037 (citing *American Power & Light*, 329 U.S. at 105). In *American Power & Light*, for example, plaintiffs challenged what they characterized as "an unconstitutional delegation of legislative power to the Securities and Exchange Commission because of an alleged absence of any ascertainable standards for guidance in carrying out its functions." 329 U.S. at 104. Plaintiffs argued that statutory standards allowing the SEC, for example, to "act so as to ensure that the corporate structure or continued existence of any company in a particular holding company system does not 'unduly or unnecessarily complicate the structure'" were "undefined" in the statute, "legally meaningless in themselves," and "carry with them no historically defined concepts." *Id.* The Supreme Court removed plaintiffs' blinders, and considered the statutory scheme *as a whole* to provide an intelligible principle, explaining that the challenged standards "need not be tested in isolation," and that they "[t]hey derive much meaningful content from the purpose of the Act, its factual background and the statutory context in which they appear." *Id.* at 104-105.

The Fifth Circuit has done the same. For example, in *United States v. Whaley*, in rejecting a nondelegation challenge to SORNA (as the Supreme Court did later in *Gundy*), the Fifth Circuit relied

solely on broad notions of statutory purpose: "SORNA's statement of purpose, to 'establish[] a comprehensive national system' of sex offender registration to 'protect the public from sex offenders and offenders against children,' 42 U.S.C. § 16901, is an intelligible principle that guides the Attorney General in exercising his discretion." 577 F.3d 254, 264 (5th Cir. 2009); *accord Womack*, 654 F.2d at 1037; *United States v. Gordon*, 580 F.2d 827, 839-40 (5th Cir. 1978) ("[W]hen considering an attack on congressional delegation, we must not only examine the entire Act to determine what standards, if any, have been provided but also whether such standards are sufficiently definite in light of the complexity of the area at which the legislation is directed and the susceptibility to change of the area in question.") (citing *United States v. Pastor*, 557 F.2d 930, 941 (2d Cir. 1977) ("Although defendants claim that the 'potential for abuse' standard . . . is impermissibly vague, the accompanying standards in that section and other sections, as well as the detailed legislative history relating directly to the phrase, adequately provide a clear and precise measure of Congress' intent and a reasonably certain guide for the Attorney General.")).

Although the Supreme Court in *Gundy* also addressed other considerations in rejecting a nondelegation challenge to SORNA, the lead opinion endorsed the same reasoning used by the Fifth Circuit in *Whaley* about the relevance of Congress's purpose. *See Gundy*, 139 S. Ct. at 2127 (plurality op.) ("[T]he mismatch between SORNA's statement of purpose and Gundy's view of § 20913(d) is as stark as stark comes. Responding to that patent disparity, Gundy urges us to ignore SORNA's statement of purpose because it is 'located in the Act's preface' rather than 'tied' specifically to § 20913(d). But the placement of such a statement within a statute makes no difference. *See* A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 220 (2012). Wherever it resides, it is 'an appropriate guide' to the 'meaning of the [statute's] operative provisions.' *Id.* at 218.") (internal citation omitted).

This approach is unsurprising: nondelegation "jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives." *Mistretta*, 488 U.S. at 372. So notwithstanding Plaintiffs' objections to being subject to FDA oversight in part because of what they describe as "FDA's unilateral policy choice," Pls.' Br. at 41, in fact, the Supreme Court's decisions "do not at all suggest that delegations of this type may not carry with them the need to exercise judgment on matters of policy," *Mistretta*, 488 U.S. at 378.

b. The Tobacco Control Act—interpreted as a whole, and with an eye toward its context and purpose—readily supplies the general policy that Congress intended the Secretary to pursue, and thus fits comfortably within this lenient doctrinal framework. At the outset, Congress included in the text of the TCA an express and detailed recitation of its purposes:

> (1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division;
>
> (2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;
>
> (3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;
>
> (4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;
>
> (5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;
>
> (6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;
>
> (7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

> (8) to impose appropriate regulatory controls on the tobacco industry;
>
> (9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and
>
> (10) to strengthen legislation against illicit trade in tobacco products.

Pub. L. No. 111-31 § 3 (*codified at* 21 U.S.C. § 387 (notes)). Each of these statutory purposes informs FDA's exercise of the authority that is delegated in 21 U.S.C. § 387a(b)—and in fact is codified in the notes to the same section of the U.S. Code, *see id.* § 387 (notes). And each supports the FDA's decision to bring e-cigarettes within the ambit of the TCA. It is thus simply untrue that Congress provided "no guidance for the exercise of discretion." Pls.' Br. at 9.

Congress also authorized the FDA to "require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health." 21 U.S.C. § 387f(d)(1). That language echoes the more general task that Congress has identified as the FDA's core mission: to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." *Id.* § 393(b)(1).

In addition, Congress delegated to the FDA—in a provision relied upon in the deeming rule, 81 Fed. Reg. at 28,982—"[t]he authority to promulgate regulations for the efficient enforcement of [the FDCA]." 21 U.S.C. § 371(a). Courts have held that this "efficient enforcement" requirement in section 371(a) requires consideration of "whether the statutory scheme as a whole"—including its purpose—"justified promulgation of the regulation." *Nat'l Confectioners Ass'n v. Califano*, 569 F.2d 690, 693 (D.C. Cir. 1978) (quoting *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 163 (1967)); *see also id.* at 695 ("[T]he regulation must be consistent with Congressional intent and the substantive provisions of the whole statute.").

In sum, notwithstanding Plaintiffs' desire to see the language in 21 U.S.C. § 387a(b) "tested in isolation," the TCA's deeming authority in fact "derive[s] much meaningful content from the purpose of the Act, its factual background and the statutory context in which [it] appear[s]." *American Power & Light*, 329 U.S. at 104-105. And "examin[ing] the entire Act," it is clear that Congress's overall guidance to FDA was "sufficiently definite." That is particularly true "in light of the complexity of the area at which the legislation is directed and the susceptibility to change of the area in question," *Gordon*, 580 F.2d at 839-40. E-cigarettes only had a *de minimis* presence in North America until years *after* the TCA's enactment, which validates Congress's choice to leave FDA with "flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote" new tobacco products, Pub. L. No. 111-31 § 3(4)—and to ensure that regulators can keep up with technological changes in this fast-moving industry.

c. At a minimum, the general policy that Congress adopted—that is, promoting the public health through efficient enforcement of the statutory requirements that Congress imposed upon the tobacco industry—is more than sufficient given the limited scope of the authority delegated in 21 U.S.C. § 387a(b). Plaintiffs concede (Pls.' Br. at 34) that "the degree of agency discretion that is acceptable varies according to the scope of the power" delegated. *American Trucking*, 531 U.S. at 475. When Congress grants the Executive sweeping authority—such as power to "set[] air standards that affect the entire national economy"—Congress "must provide substantial guidance" to the agency. *Id.* By contrast, when Congress confers narrow authority—such as the discretion to define a single statutory term—it "need not provide any direction." *Id.* Put differently, "the question to be asked is not whether there was any explicit principle telling the" Executive how to exercise its statutory discretion, "but whether any such guidance was needed, given the nature of the delegation and the officer who is to exercise the delegated authority." *Loving v. United States*, 517 U.S. 748, 772 (1996).

Loving, for example, upheld a statute authorizing the President to select aggravating factors for the death penalty in military cases. *Id.* at 771-774. The absence of any specific statutory direction concerning how to select those factors was immaterial because "the delegation [was] set within boundaries the President may not exceed" and because the delegation fell within the "traditional authority" of the Executive official at issue. *Id.* at 772. Here, as in *Loving*, the limited scope of the authority delegated by 21 U.S.C. § 387a(b) made detailed statutory direction unnecessary. FDA's discretion is confined "to a narrow and defined category," *Ambert*, 561 F.3d at 1214, of tobacco products: those other than "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" that also meet the definition of a "tobacco product" in 21 U.S.C. § 321(rr)(1). And even FDA's authority with respect to that subset of "tobacco products" is limited to determining whether they must comply with the TCA's requirements—all of which were spelled out by Congress in the statute itself. 21 U.S.C. § 387a(b) does not empower the FDA to impose additional obligations—it authorizes only a determination whether certain "tobacco products" should be required to comply with all of the TCA's provisions, or instead should be entirely exempt. And that limited, binary discretion fits comfortably within FDA's traditional (and congressionally defined) mission: to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Given the narrow scope of the delegated authority, no more specific congressional "direction," *American Trucking*, 531 U.S. at 475, was needed.

21 U.S.C. § 387a(b) is no different for nondelegation purposes from a (hypothetical) statute that delegated discretion to *exempt* otherwise-presumptively-covered "tobacco products" (or specific manufacturers) from compliance with the TCA's requirements. And in fact, many statutes authorize the Executive to grant exemptions or waivers from otherwise generally applicable statutory

requirements (on either a categorical, or a one-off basis)[20]—a practice that is, in substance, "little more than a formalized version of the time-honored practice of prosecutorial discretion." *Reynolds v. United States*, 565 U.S. 432, 450 (2012) (Scalia, J., joined by Ginsburg, J., dissenting). Congress could have adopted that approach here without altering the actual extent of the agency's authority, which further underscores the unremarkable nature of the narrow authority at issue. *Cf. id.* (observing that "giv[ing] the Attorney General the power to reduce congressionally imposed requirements" would "'pose[] no constitutional question'" under the nondelegation doctrine (citation and emphasis omitted)).

iv. Plaintiffs' contrary arguments lack merit.

a. Unsurprisingly, Plaintiffs try to analogize the Tobacco Control Act to the statute at issue in the only two cases in which the Supreme Court has ever found a violation of the nondelegation doctrine: *Panama Refining* and *Schechter Poultry*. *See* Pls.' Br. at 33, 36-41. Both cases were decided in 1935, and both concerned the Recovery Act, a comprehensive law "to regulate the entire economy" enacted at the beginning of the Franklin D. Roosevelt Administration and in the depths of the Great Depression. *American Trucking*, 531 U.S. at 474. The flaw identified in each provision was that "Congress had failed to articulate *any* policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power." *Mistretta*, 488 U.S. at 373 n.7 (emphasis added). By contrast here, Congress expressly stated its goals in enacting the TCA, and also defined the boundaries of the key statutory term ("tobacco product") with respect to which authority was delegated. The TCA bears little resemblance to the rudderless grants of authority in the Recovery Act.

[20] *See, e.g.*, 7 U.S.C. § 1637b(b)(2)(D) (reporting requirements for small dairy producers); 15 U.S.C. § 78u-5(g) (various securities-law requirements); 15 U.S.C. § 78j-1(m)(3)(C) (audit-committee independence requirements); 15 U.S.C. § 5711(a)(5) (requirements on pay-per-call services); 16 U.S.C. § 823a(b) (requirements for hydroelectric facilities); 29 U.S.C. § 1112(e) (bonding requirements for employee-benefit plans); 46 U.S.C. § 4305 (recreational-vessel requirements); 49 U.S.C. §§ 20306, 47528(b) (railroad-equipment and aircraft-noise-control requirements).

Panama Refining involved Section 9(c) of the Recovery Act, which authorized the President "to prohibit the transportation in interstate and foreign commerce of petroleum . . . withdrawn from storage in excess" of state-set quotas and also specified a penalty for violating any such potential prohibition. 293 U.S. at 406 (citation omitted). The Supreme Court held the law invalid because it "establishe[d] no criterion to govern the President's course." *Id.* at 415. The Recovery Act's goals also did nothing to inform the President's decisionmaking. Its "general outline of policy . . . favor[ed] the fullest possible utilization of the present productive capacity of industries" to mobilize the economy and speed economic recovery. *Id.* at 417-418. But, oddly, Section 9(c) then asked the President to determine instances in which such "fullest possible utilization"—*i.e.*, marketing oil above State-imposed quotas—should be a *crime*. *Id.* at 418. Virtually any invocation of the Executive's power therefore would have been in substantial tension with the Recovery Act's central goal, and the Court concluded that the statute gave no indication of the countervailing "circumstances or conditions in which" departing from that central purpose would be warranted. *Id.* at 417. Here, by contrast, Congress wanted, among other things, "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco," Pub. L. No. 111-31 § 3(2). FDA's science-based judgment to exercise its statutory authority to "deem" e-cigarettes to be a "tobacco product" subject to the TCA's requirements is fully consistent with Congress's objectives. *Nicopure*, 266 F. Supp. 3d at 395 n.26 ("[T]he Secretary's decision to deem e-cigarettes to be tobacco products, and therefore subject to premarket review, is reasonable and fully consistent with the intent of the statute.").

Plaintiffs suggest a more exacting version of the nondelegation doctrine, in part by reimagining "the statute declared unconstitutional in *Panama Refining*" as one that "did *not* confer limitless authority on the President to regulate any industry in any way he saw fit," but rather "was constrained to only a

subset of petroleum products . . . ." Pls.' Br. at 38-39 (emphasis added). But whether or not Plaintiffs' interpretation of that statutory scheme is defensible, it is plainly not shared by the Supreme Court, which has (more than once) described the statute at issue in *Panama Refining* as having "provided literally no guidance for the exercise of discretion." *American Trucking*, 531 U.S. at 474; *accord Mistretta*, 488 U.S. at 373 n.7 ("In *Schechter* and *Panama Refining* the Court concluded that Congress had failed to articulate *any* policy or standard that would serve to confine the discretion of the authorities to whom Congress had delegated power.") (emphasis added).

Schechter Poultry is even further afield—as Plaintiffs seem to recognize (barely discussing it in their brief). There, the Supreme Court reversed convictions under the Code of Fair Competition for the Live Poultry Industry, promulgated under Section 3 of the Recovery Act. *Schechter Poultry*, 295 U.S. at 521. Section 3 permitted a trade association to write a code of fair competition to govern its own industry and ask the President to approve it. *Id.* at 521 n.4. The President could approve the proposed code so long as the trade association "impose[d] no inequitable restrictions on admission to [its] membership" and the code was "not designed to promote monopolies." *Id.* at 522 (citation omitted). The Live Poultry Code set rules encompassing everything from laborers' working hours and conditions, to quality control, to a requirement that prohibited wholesalers from allowing retailers to select individual chickens (rather than purchasing whole or half coops). *Id.* at 524-528.

The Supreme Court held that Congress had not "established the standards of legal obligation" because it had not provided "any adequate definition of the subject to which the codes [were] to be addressed" and did "not define 'fair competition.'" *Id.* at 530-531. Section 3 "supplie[d] no standards for any trade, industry or activity," instead granting the President "virtually unfettered" discretion. *Id.* at 541-542. And it "prescribed no method of attaining" its goal of "rehabilitat[ing] industry"; provided no limitations on the "nature" of the codes that could be created; and "delegated, not to a public

official responsible to Congress or the Executive, but to private individuals engaged in the industries to be regulated" the power to write the codes. *Yakus*, 321 U.S. at 424 (discussing *Schechter Poultry*); *see Dep't of Transp. v. Ass'n of Am. R.R.*, 135 S. Ct. 1225, 1237-1238 (2015) (Alito, J., concurring) (distinguishing delegations to federal agencies from those to nongovernmental entities).

The Tobacco Control Act suffers from none of those flaws. Congress specifically delineated the subject that FDA is authorized to address: the applicability of the TCA's requirements to a well-defined subset of "tobacco products." Congress also identified both the high-level statutory objectives, and the precise methods of attaining them: by requiring manufacturers to obtain premarket authorization before tobacco products may be sold, by ensuring accurate warning labels, and by requiring disclosure of all ingredients and additives, among many other specific—and congressionally imposed—requirements. And unlike the Recovery Act, the TCA delegates no authority to any private entity, but only to subject-matter experts within the Executive Branch. 21 U.S.C. § 387a(b) is therefore far removed from the provisions in *Panama Refining* and *Schechter Poultry* that exceeded the outer limits of Congress's broad delegation powers—even taking those precedents at face value, and ignoring the 0% success rate on nondelegation claims in the intervening 84 years.

b. Plaintiffs claim that "the *FDA itself* is on record stating that its deeming authority is not constrained by any policy parameters." Pls.' Br. at 35. But the quotes Plaintiffs rely on (primarily from a brief filed in another case) explicitly reference the (undisputed) reality that only a "tobacco product" may be "deemed" subject to the TCA—itself a significant "cabin[ing] [of] the agency's discretion" that is sufficient to disprove Plaintiffs' superficial reading of the FDA's prior statements. Pls.' Ex. 14 (ECF No. 15-14 at 39-40). Those excerpts are also presented to this Court shorn from their context: an *unsuccessful* argument that FDA's decision to "deem" new tobacco products was "committed to agency discretion by law" under 5 U.S.C. § 701(a)(2). The Government routinely

argues that certain agency decisions fall within that statutory exception to judicial review under the Administrative Procedure Act (APA). If the Government merely *advancing* that argument were enough to create a nondelegation problem, the Supreme Court's nondelegation precedent would look quite different. In reality, however, many delegations of discretionary authority that are entirely consistent with the (comparatively lenient) nondelegation doctrine will still provide an agency with authority that is sufficiently flexible to be considered "committed to agency discretion by law" under the APA. *See, e.g.*, *Nat'l Fed'n of Fed. Emps. v. United States*, 905 F.2d 400, 404-405 (D.C. Cir. 1990) (holding both (1) that Congress supplied an "intelligible principle" to govern process of military base closures and (2) that the decision to close a military base was not subject to any "judicially manageable standards" and was thus "committed to agency discretion by law" under Section 701(a)(2) of the APA).

In any event, although it requires carefully parsing footnotes to learn this from Plaintiffs' brief, *see* Pls.' Br. at 35 n.20, in fact, the *Nicopure* court *rejected* this argument, holding instead that "the decision [was] reviewable," because "when the Secretary exercised the authority to 'deem' e-cigarettes to be tobacco products, the agency was interpreting the statutory definition of 'tobacco product.'" *Nicopure*, 266 F. Supp. 3d at 393. And although *Nicopure* is now before the D.C. Circuit, neither side has raised this issue on appeal. Nor did any party ever raise the nondelegation doctrine in *Nicopure*—as Plaintiffs concede. *See* Pls.' Br. at 35 n.20. Ultimately, this Court need only look to the Tobacco Control Act itself—and the briefs filed in *this* case—to decide whether the TCA should become only the second law in history (and the first since 1935) to violate the nondelegation doctrine.

* * *

"Respect for a coordinate branch of Government forbids striking down an Act of Congress except upon a clear showing of unconstitutionality." *Salazar v. Buono*, 559 U.S. 700, 721 (2010). Plaintiffs have not come close to that showing here. Ultimately, Plaintiffs make no secret of their

view that "the current standard applied by courts is unduly permissive and the nondelegation doctrine should be more vigorously enforced by the judiciary." Pls.' Br. at 43 n.25. But that "permissive" standard is fully binding on this Court. Plaintiffs' complaint should be dismissed.[21]

II. PRELIMINARY INJUNCTIVE RELIEF IS NOT WARRANTED.

As explained above, this lawsuit should be dismissed in its entirety for failure to state a claim, and Plaintiffs' motion for a preliminary injunction can then be denied as moot. In the alternative, Plaintiffs have also failed to carry their burden to justify the "extraordinary remedy," *Winter*, 555 U.S. at 24, of a preliminary injunction. Plaintiffs are unlikely to succeed on the merits, for all the reasons explained above—an independent basis for denial of their motion. *See Jordan*, 823 F.3d at 809. To the extent the Court goes on to consider the remaining preliminary-injunction factors, each passing day underscores the urgency of the FDA's efforts to protect the public health by imposing at least some oversight of these novel products. Plaintiffs' pessimistic prognostications about the looming disappearance of all e-cigarettes are undermined by market leaders' public confirmations that they are prepared to meet the May 2020 application deadline, and that they intend to *voluntarily* cease sales of some flavored products—ending any speculation that a "mass-market exit" is imminent as a result of FDA enforcement. Moreover, Plaintiffs' decision to wait more than three years to bring a facial constitutional challenge to a regulation to which they have been subject since 2016 undermines their claim that imminent irreparable harm now justifies the extraordinary remedy of a preliminary injunction invalidating the deeming rule in its entirety. And as for irreparable harm, Plaintiffs' showing is premised on speculative concerns about the impact of *future* exercises of FDA's enforcement

[21] Plaintiffs' only other claim purports to be brought under the Declaratory Judgment Act. Compl. ¶¶ 66-68. But "although the Declaratory Judgment Act provides a *remedy* different from an injunction[,] it does not provide an additional cause of action with respect to the underlying claim." *Okpalobi v. Foster*, 244 F.3d 405, 423 n.31 (5th Cir. 2001). That claim therefore necessarily rises or falls with the merits of Plaintiffs' non-delegation claim, and should also be dismissed for the same reasons.

discretion, primarily a new "compliance policy" that has been discussed in the press but has not actually been issued, and therefore is currently causing no legally cognizable harm. For those reasons, and as explained further below, Plaintiffs are not entitled to a preliminary injunction.

A. The requested preliminary injunction would disserve the public interest.

Plaintiffs have failed to carry their burden to show that a preliminary injunction would serve the public interest, which is an independent basis for denial of their motion. *See Jordan*, 823 F.3d at 809 (no preliminary-injunction motion should be "granted unless the party seeking it has clearly carried the burden of persuasion on *all four* requirements") (emphasis added). When it proposed the deeming rule, FDA noted that the overall public-health impact of e-cigarettes would crucially depend upon

> who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net impact at the population level to be positive. If, on the other hand, there is significant initiation by young people, minimal quitting, or significant dual use of combustible and non-combustible products, then the public health impact could be negative.

79 Fed. Reg. 23141, 23147 (Apr. 25, 2014). Unfortunately, recent data regarding youth usage of e-cigarettes present a troubling picture,[22] and the claim that vaping helps smokers quit in meaningful numbers remains unproven. The precise risk profile presented by these products remains unknown, but there are many reasons to be gravely concerned, *see, e.g.*, *supra* at 2 n.2, n.3—especially without oversight by the FDA to ensure, at a minimum, that the most dangerous and youth-friendly products

[22] *See, e.g.*, FDA, *2018 E-Cigarette Data* (Nov. 2018) ("Current e-cigarette use among middle and high school students increased alarmingly between 2017 and 2018."), *available at* https://www.fda.gov/media/120063/download; *see also* Cullen, *et al.*, *e-Cigarette Use Among Youth in the United States, 2019*, JAMA (Nov. 2019) (describing continued high prevalence of e-cigarette use by high school students into 2019), *available at* https://jamanetwork.com/journals/jama/fullarticle/2755265; Leventhal, *et al.*, *Flavors of e-Cigarettes Used by Youths in the United States*, JAMA (Nov. 2019) ("Adolescent e-cigarette use has increased substantially since 2016."), *available at* https://jamanetwork.com/journals/jama/fullarticle/2755264.

and practices can be held in check. Accordingly, notwithstanding prior exercises of enforcement discretion, and as the FDA has increasingly signaled to the general public in recent months and years,[23] the agency now believes that earlier and more substantial regulatory scrutiny of these products is warranted.[24] Those science-based policy judgments about FDA's enforcement discretion merit substantial deference. *Cf. Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) ("[A] reviewing court must remember that the Commission is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, . . . a reviewing court must generally be at its most deferential.").

Plaintiffs assert that there is a "public interest in maintaining ENDS products on the market" because "some adults" might use e-cigarettes as part of an effort "to transition away from combusted tobacco use." Pls.' Br. at 51 (quoting 81 Fed. Reg. at 28,977). But regardless of how this case is resolved, the entire vaping industry is not going to precipitously disappear, and adult smokers who wish to switch to e-cigarettes will continue to have that option. Among others, JUUL—which reportedly ended 2018 with an overwhelming 76% market share[25]—apparently is prepared to comply with the May 2020 deadline for premarket applications, and is "fully committed to the current PMTA process" and "confident in the content and quality of the materials [it] will submit with [its] application by May 2020." *Our Commitment to the PMTA Process*, JUUL Labs (Aug. 20, 2019), *available at*

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[23] FDA, Draft Guidance: *Modifications to Compliance Policy for Certain Deemed Tobacco Products* (Mar. 2019), *available at* https://www.fda.gov/media/121384/download.

[24] *See* HHS, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019), *available at* https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html.

[25] Richard Craver, *Juul ends 2018 with 76 percent market share*, WINSTON-SALEM JOURNAL (Jan. 8, 2019), *available at* https://www.journalnow.com/business/juul-ends-with-percent-market-share/article_6f50f427-19ec-50be-8b0c-d3df18d08759.html.

https://newsroom.juul.com/2019/08/20/our-commitment-to-the-pmta-process/. There have been similar reports about NJOY (which reportedly has approximately 12% of the market share).[26] In fact, at least one major tobacco company has *already* submitted a PMTA for its e-cigarette products.[27] Accordingly, even if every other manufacturer goes out of business—a highly speculative proposition—many e-cigarette products are likely to remain on the market, even in the face of increased FDA enforcement of premarket authorization requirements. Denying Plaintiffs' motion therefore does not create any meaningful risk that adult e-cigarette users will be forced to return to combustible cigarettes *en masse* because of an overnight disappearance of this entire industry.

With respect to flavored vaping products, market leaders are already *voluntarily* stepping back from selling flavored products as a result of concerns about their popularity among youth.[28] So whatever impact any future compliance policy might have on Plaintiffs or their competitors, plentiful options will remain on the market for adults who are currently addicted to cigarettes and wish to start (or continue) vaping. And FDA remains committed to working with Plaintiffs, or with any business

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[26] *See* Juliet Chung & Jennifer Maloney, *E-Cigarette Maker NJOY Changes Funding Plan After Vaping Ban*, THE WALL STREET JOURNAL (Sept. 13, 2019) ("NJOY plans to file applications for all of its products early next year . . . . Juul and NJOY both believe the crackdown could be good for them over the long term, because it could clear out counterfeit, child-friendly and potentially hazardous products and allow only regulated products to remain . . . ."), *available at* https://www.wsj.com/articles/e-cigarette-maker-njoy-changes-funding-plan-after-vaping-ban-11568410278.

[27] *See* Jennifer Maloney, *Reynolds Files for FDA Review of Vuse E-Cigarettes*, THE WALL STREET JOURNAL (Oct. 11, 2019) ("Tobacco giant Reynolds American Inc. submitted an application for some of its Vuse e-cigarettes to the Food and Drug Administration, gaining a head start on other major e-cigarette makers in seeking permission to keep its vaping products on the market."), *available at* https://www.wsj.com/articles/reynolds-files-for-fda-review-of-vuse-e-cigarettes-11570808409.

[28] *See JUUL Labs suspends sale of non-tobacco, non-menthol-based flavors in the U.S.*, JUUL Labs (Oct. 17, 2019) (announcing "the suspension of the sale of [JUUL's] non-tobacco, non-menthol-based flavors (Mango, Creme, Fruit, and Cucumber) in the U.S., pending FDA review" and that JUUL is "refraining from lobbying the Administration on its draft flavor guidance and will fully support and comply with the final policy when effective"), *available at* https://newsroom.juul.com/juul-labs-suspends-sale-of-non-tobacco-non-menthol-based-flavors-in-the-u-s/.

(large or small) that wishes to sell its products in compliance with federal law, and in a manner that is appropriate for the protection of the public health.

Plaintiffs' requested relief—vacatur of the deeming rule in its entirety, and an order "enjoin[ing] Defendants from exercising *any* authority over *any* 'tobacco products' deemed to be subject to the TCA pursuant to Defendants' power under § 387a(b)," Pls.' Br. at 53 (emphases added)—would leave this novel and massive industry *entirely free* from meaningful federal scrutiny. Indeed, at least as a matter of federal law, there would no longer be any prohibition on the sale of e-cigarettes to minors. Even if reasonable minds might differ regarding the optimal approach to regulation of this industry, surely at least *some* FDA oversight of *some* of these potentially harmful products is in the public interest—at least with respect to the most dangerous and youth-friendly products and marketing practices. But granting Plaintiffs' motion would prohibit the FDA from carrying out its mission, mandated by Congress, to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). And it would undermine one of Congress's primary goals in enacting the Tobacco Control Act: "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco." Pub. L. No. 111-31 § 3(2).

Finally, Plaintiffs argue at length that there is a "public interest in preserving the separation of powers" mandated by the Constitution. Pls.' Br. at 50. The Government has no quarrel with that general proposition, but it begs the central question in this case. And for the reasons stated above, the Tobacco Control Act is entirely consistent with our constitutional structure.

* * *

"[A]n evaluation of the public interest should be given considerable weight in determining whether a motion for preliminary injunction should be granted." *Texas v. United States*, 328 F. Supp. 3d 662, 678, 741 (S.D. Tex. 2018) (denying motion for preliminary injunction even after finding that movants had "established a substantial likelihood of success on the merits"). And here, the public interest—indeed, the public health—would be threatened by Plaintiffs' request to vacate the deeming rule in its entirety and to enjoin FDA from enforcing the Tobacco Control Act *at all* with respect to the fastest-growing segment of the tobacco market. Plaintiffs' motion can be denied on that basis alone—regardless of the Court's views on the legal merit of Plaintiffs' nondelegation claim.

B. Plaintiffs have unreasonably delayed in seeking a preliminary injunction.

There is another, independent reason to deny Plaintiffs' preliminary-injunction motion: their unreasonable delay in seeking relief. "A long delay by plaintiff after learning of the threatened harm may be taken as an indication that the harm would not be serious enough to justify a preliminary injunction." *Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 297 (5th Cir. 2012) (quoting 11A Charles Alan Wright et al., Federal Practice and Procedure § 2948.1 (2d ed. 1995)); *Gonannies, Inc. v. Goupair.Com, Inc.*, 464 F. Supp. 2d 603, 609 (N.D. Tex. 2006) ("[D]elay in seeking a remedy is an important factor bearing on the need for a preliminary injunction."). Thus, the Fifth Circuit has held that where a plaintiff "waited three months before petitioning the district court for temporary relief," the delay was "evidence" of a lack of irreparable harm. *Boire v. Pilot Freight Carriers, Inc.*, 515 F.2d 1185, 1193 (5th Cir. 1975).

Here, any injury caused by the deeming rule itself would have commenced no later than the rule's taking effect over *three years ago*. As for Plaintiffs' more recent alleged harms, any burdens associated with an accelerated compliance date for premarket tobacco applications (*see* Pls.' Br. at 47-

48) would have been apparent months ago. *See AAP*, 2019 WL 3067492, at *7 (ordering the new deadline in a July 12, 2019 order). And even accepting uncritically the (necessarily speculative) proposition that future guidance modifying enforcement priorities with respect to "flavored" e-cigarettes will cause a future injury to Plaintiffs once any such guidance is actually finalized, issued, and its effective date arrives, *see* Pls.' Br. at 46-47; *but see infra*, Section II(C), the (potential) changes Plaintiffs now fear were announced publicly on September 11, 2019[29]—and Plaintiffs *still* waited another month to file their motion. These delays undermine any claim of irreparable harm that would justify the "extraordinary remedy" of a preliminary injunction. *Winter*, 555 U.S. at 24.

C. FDA's proposed compliance policy, which has not yet been issued, is not causing any legally cognizable harm to Plaintiffs, and in any event is not challenged in the complaint.

i. Plaintiffs' motion for a preliminary injunction (Pls.' Br. at 46-47), as well as their opposition to the Government's recent extension motion, ECF No. 21, make clear that their desire for preliminary relief primarily stems from recent statements from government officials suggesting that the FDA intends to finalize and publish guidance in the coming weeks setting forth its enforcement priorities with respect to flavored vaping products. To be clear, as of the date of this filing, any such new guidance *currently does not exist*, and is therefore causing no harm to Plaintiffs (and certainly none of the "irreparable" or "legally cognizable" sort). Plaintiffs implicitly concede as much, asserting only that they fear some *future* harm. *See* Pls.' Opp'n to Defs.' Mot. for Extension, at 4 ("The mere *release* of the revised policy *will* cause immediate irreparable injury . . . .") (second emphasis added).

[29] HHS, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019), *available at* https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html.

Defendants do not dispute that senior government officials have long stated that a revised compliance policy (published in draft form in March of 2019) is forthcoming.[30] And Plaintiffs are correct that the FDA is concerned about flavored e-cigarettes, which appeal strongly to youth, according to recent peer-reviewed studies[31]—data consistent with the regulatory history of traditional cigarettes, for which *all* flavors other than tobacco and menthol are already banned entirely, 21 U.S.C. § 387g(a)(1)(A). But the precise contours of any future policy are (necessarily) uncertain until new guidance is actually issued. And both the draft guidance and the statements from government officials on which Plaintiffs rely suggest that there will be some period of time after issuance of any new guidance before it will be implemented. *See* March 2019 Draft Guidance at 12 ("beginning 30 days after this guidance is finalized"); *accord Remarks by President Trump in Meeting on E-Cigarettes* (Sept. 11, 2019) (Secretary Azar: "there will likely be about a 30-day delayed effective date"), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trump-meeting-e-cigarettes/.

Even *after* any new enforcement policy is issued, under the TCA, any manufacturers, including "flavored product manufacturers[,] can, at any time," apply for FDA authorization to market their

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[30] *See* FDA, *FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access* (Sept. 11, 2018) ("The FDA now believes that youth use of e-cigarettes is reaching epidemic proportions. . . . To address these trends, . . . the FDA is re-examining its compliance policy dates for the submission of premarket tobacco applications to the FDA for certain e-cigarettes."), *available at* https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more; *see also* FDA, Draft Guidance for Industry, *Modifications to Compliance Policy for Certain Deemed Tobacco Products* (March 2019), *available at* https://www.fda.gov/media/121384/download.

[31] *See, e.g.*, Andrea C. Villanti *et al.*, *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, JAMA Network Open, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (Oct. 23, 2019) ("In this cohort study of 11,996 youth and 26,447 adults . . . most youth and young adult new tobacco users first tried a flavored product. First use of flavored tobacco products was positively associated with subsequent product use compared with first use of a nonflavored product."), *available at* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396#229621079.

products. *Id.* (statement of Secretary Azar). And if a manufacturer can carry its burden—imposed by Congress in the Tobacco Control Act, not by the FDA—to demonstrate that the sale of its products is "appropriate for the protection of the public health," 21 U.S.C. § 387j(b)-(c), then they may be lawfully sold. But with or without any new enforcement guidance, under the plain terms of the Tobacco Control Act, *any* deemed tobacco products on the market without FDA authorization—which is *all* e-cigarette products currently on the market—are unlawful. *See id.* § 387j(a)(1)-(2). To be sure, FDA has not yet enforced this requirement against these particular Plaintiffs (or most similar businesses), as a matter of its publicly announced enforcement discretion. But the FDA's temporary forbearance from enforcement of the law does not *change* the law.

In any event, whatever may be said of Plaintiffs' concerns about a new compliance policy, any such (future) policy is not challenged in the complaint. Nor could it have been, given the obvious Article-III ripeness problem (among other legal obstacles) with challenging a non-existent guidance document, the contents of which Plaintiffs are speculating about based only upon press reports. *See, e.g.*, *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 807-08 (2003) ("Ripeness is a justiciability doctrine designed 'to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.'") (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-149 (1967)). Instead, Plaintiffs have filed a facial constitutional challenge to one specific provision of the Tobacco Control Act (21 U.S.C. § 387a), and have requested vacatur of one rule issued pursuant to that allegedly unconstitutional "deeming" authority.[32] So the Court need not burden itself with

[32] *See* Compl., Prayer ¶ 1 ("Declare Section 901 of the TCA, codified at 21 U.S.C. § 387a, to be in violation of Article I of the Constitution of the United States, and, consequently, the Deeming

predictions about any future policy, for the simple reason that Plaintiffs may not obtain a preliminary injunction based on allegations that sweep beyond the scope of the complaint itself. *See, e.g.*, *Bucklew v. St. Clair*, No. 3:18-cv-2117-N (BH), 2019 WL 2251109, at *2 (N.D. Tex. May 15, 2019) (collecting cases, and noting that "district courts within this circuit have found that a request for preliminary injunction must [ ] be based on allegations related to the claims in the complaint"), *report and recommendation adopted*, 2019 WL 2249719 (N.D. Tex. May 24, 2019).

ii. Finally, as part of their showing of harm, Plaintiffs also rely on the May 2020 deadline for submission of premarket tobacco applications. Pls.' Br. at 47-48. That deadline was set not by the FDA, but by another federal court. *See* Pls.' Br. at 18 ("FDA has now been ordered by the federal district court for the District of Maryland to severely accelerate the compliance deadlines."); *see also AAP*, 2019 WL 3067492, at *7; Order at 2, ECF No. 158, *Cigar Ass'n of Am. v. FDA*, No. 16-1460 (D.D.C. Oct. 18, 2019) ("[T]he *AAP* court's decision is the cause of Plaintiffs' claimed harm, not any agency action"). But even setting that aside, at the absolute latest, Plaintiffs have been on notice of their statutory obligations (imposed by the TCA) to obtain premarket authorization since May 2016, when the final deeming rule was published, 81 Fed. Reg. at 28,974—that is, even ignoring the notice of proposed rulemaking published in April 2014 in substantially similar form, 79 Fed. Reg. at 23,142. Any prudent manufacturer would have started this process long ago—and at least some apparently did, *see supra* at 44 n.27 (e-cigarette PMTA application submitted in October 2019).

In any event, it appears that timing is not the real problem: Plaintiffs have strongly hinted that they have no intent to *ever* prepare premarket applications consistent with the requirements in the

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Rule promulgated under its authority to be invalid."); *see also* Pls.' Br. at 53 ("Plaintiffs respectfully request that the Court preliminarily enjoin Defendants from exercising any authority over any 'tobacco products' deemed to be subject to the TCA pursuant to Defendants' power under § 387a(b) of the TCA, including, but not limited to, the current Deeming Rule and any enforcement of same.").

Tobacco Control Act (at least for the vast majority of their products), and that delay-by-litigation is now their primary business strategy:

> Even if the PMTA requirements were finalized and there were time to perform the required tests and prepare the application, due to PMTA cost alone, I would have to reduce the product line to fewer items.
>
> I have spoken with dozens of other vape shop owners about how to possibly try to comply with the PMTA requirements. The only realistic option anybody sees is simply preparing something to submit by the deadline and hoping that it is accepted for review, to buy time during the FDA's review process. It appears absolutely impossible to complete the tests the FDA wants, and submit an application that meets all of the specific requirements summarized by FDA. Thus, our only hope would be to submit what we can, and hope we win in litigation or the rules are otherwise changed during the process.

Decl. of B. Dudziak & Big Time Vapes, Inc., ECF No. 15-9, ¶ 6(b)-(c); *see also, e.g.*, Decl. of Mega Vape LLC, ECF No. 15-8, ¶ 6(d) ("The only realistic option I can see would be to pay for lawyers and consultants to help prepare whatever limited tests and documents we could assemble and submit a PMTA for a single product by the deadline, and hope that either we win in litigation or the rules are changed to be more realistic."). The Court should not reward that strategy with a favorable exercise of equitable discretion.

D. Plaintiffs' requested relief is overbroad.

Even if Plaintiffs could satisfy the ordinary standards for a preliminary injunction, the relief they seek is overbroad. Constitutional and equitable principles require that injunctive relief be limited to redressing a plaintiff's own cognizable injuries. *Lewis v. Casey*, 518 U.S. 343, 357 (1996). And equitable principles require that injunctions "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr.*, 512 U.S. 753, 765 (1994). Thus, any injunction should be limited to relieving the specific injury of only those Plaintiffs whom the Court determines have a cognizable claim and will suffer irreparable harm without an injunction.

CONCLUSION

Plaintiffs' complaint should be dismissed with prejudice in its entirety, and Plaintiffs' motion for a preliminary injunction should be denied.

November 6, 2019

Respectfully submitted,

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